

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 23

UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte ANNAMARIA NAGGI, ENRICO PETRELLA,
GIANGIACOMO TORRI and BENITO CASU

Appeal No. 2002-1356
Application No. 09/206,063

ON BRIEF

Before ADAMS, MILLS, and GREEN, Administrative Patent Judges.

MILLS, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. §134 from the examiner's final rejection of claims 5-22, which are all of the claims pending in this application.

Claims 5, 11 and 17 are illustrative of the claims on appeal and read as follow:

5. A method of preparing a stabilized osmotic agent comprising the following steps:
- providing a solution of starch dissolved in water and
 - adding NaBH₄ to the starch solution to reduce the starch.

11. A method of preparing a stabilized osmotic agent comprising the following steps:

providing a solution of starch dissolved in water;
providing a solution of NaOCl; and
adding the NaOCl solution to the starch solution to oxidize the starch.

17. A method of preparing a stabilized osmotic agent comprising the following step:

dissolving starch in an acid and an alcohol selected from the group consisting of methanol, butanol and glycerol.

The prior art references relied upon by the examiner are:

Horn et al. (Horn)	3,974,034	Aug. 10, 1976
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Eliasson, ed. (Eliasson), Carbohydrates in Food, Chapter 4: "Cell Wall Polysaccharide: Structural, Chemical and Analytical Aspects," Marcel Dekker, Inc., New York, pp. 191, 195 (1996)

Solomons, Organic Chemistry, 2nd ed., John Wiley and Sons, New York, p. 890 (1976)

Grounds of Rejection

Claims 5-22 stand rejected under 35 U.S.C. § 103(a) as obvious over Solomons in view of Eliasson and Horn.

We affirm the rejection as it applies to claims 5-16 and reverse the rejection as it applies to claims 17-22.

Claim Grouping

The separate patentability of each of the independent claims is argued separate and apart from each other. Brief, page 7. Dependent claims are not separately argued in the Brief. Therefore, we treat claim 5 as representative of claims 5-10, claim 11 as representative of claims 11-16, and claim 17 as representative of claims 17-22.

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Accordingly, we limit our discussion to representative claims 5, 11 and 17. In re Young, 927 F.2d 588, 590, 18 USPQ2d 1089, 1091 (Fed. Cir. 1991).

DISCUSSION

In reaching our decision in this appeal, we have given consideration to the appellants' specification and claims, to the applied references, and to the respective positions articulated by the appellants and the examiner.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the noted rejections, we make reference to the examiner's Answer for the examiner's reasoning in support of the rejection, and to the appellants' Brief for the appellants' arguments thereagainst. As a consequence of our review, we make the determinations which follow.

Background

According to appellant's specification, pages 2-3:

[c]onventional peritoneal dialysis solutions contain glucose as an osmotic agent to maintain the osmotic pressure of the solution higher than the physiological osmotic pressure (about 285 mOsmol/kg). Glucose is a preferred osmotic agent because it provides rapid ultrafiltration rates. However, certain disadvantages have become associated with the use of glucose.

For example, glucose is known to decompose to 5-hydroxymethylfurfural (5-MHF) in an aqueous solution during autoclaving or steamed sterilization.

One family of compounds capable of serving as osmotic agents in peritoneal dialysis solutions is icodextrins, including maltodextrins. However, while these compounds are suitable for use as osmotic agents,

they are also known to degrade during heat sterilization to aldonic acids and formaldehyde.

In the section entitled "Summary of the Invention", the specification indicates that the invention provides a sterilized peritoneal dialysis solution comprising a glucose polymer linked predominantly by α -1,4 bonds. Specification, page 4. In one embodiment the glucose polymer linked by α -1,4 bonds is selected from D-glucitol gluconic acid and an alkylglycoside. Specification, pages 4-5. In a further embodiment the invention reduces maltodextrin to D-glucitol linked predominantly by α -1,4 bonds using a solution of water and NaBH_4 . Specification, page 7. In another embodiment maltodextrin is oxidized to a gluconic acid linked predominantly by α -1,4 bonds using a solution of water and NaOCl . Specification, page 8. It is known in the art that maltodextrin is a starch product which consists of D-glucose units linked primarily by α -1,4 bonds.

35 U.S.C. § 103

Claims 5-22 stand rejected under 35 U.S.C. § 103(a) as obvious over Solomons in view of Eliasson and Horn.

We note our review of the present appeal has been complicated by the fact that the examiner has failed to separately address each rejection as it applies to each of the independent claims. However, we affirm the rejection of the examiner as it applies to claims 5-16 based upon the indicated strengths of the cited references.

In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden

of presenting a prima facie case of obviousness. See In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). It is well-established that the conclusion that the claimed subject matter is prima facie obvious must be supported by evidence, as shown by some objective teaching in the prior art or by knowledge generally available to one of ordinary skill in the art that would have led that individual to combine the relevant teachings of the references to arrive at the claimed invention. See In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988).

Claim 5

Claim 5 is directed to a method of preparing a stabilized osmotic agent comprising the following steps: providing a solution of starch dissolved in water and adding NaBH_4 to the starch solution to reduce the starch. We interpret the term “stabilized osmotic agents” in claim 5 to include maltodextrins reduced using water and NaBH_4 , in accordance with the specification.

According to the examiner, “the use of sodium borohydride [NaBH_4] to reduce saccharides is well known in the art as Solomons teaches that aldoses and ketoses can be reduced with sodium borohydrides.” Answer, page 4. Solomons particularly describes the reduction of D-glucose (a component of maltodextrin) to D-glucitol. Solomons, page 890. Solomons does not teach the presence of water in the reaction. According to the examiner, “Eliasson teaches that other non-cellulosic polysaccharides (e.g., arabinoxylans, xyloglucans and glucomannans) are preferentially extracted using

aqueous solutions of alkali, containing sodium borohydride. The borohydride converts the reducing end groups of the polysaccharides to a hydroxymethyl group, and this decreases the incidence of alkaline degradation. Although the α 1,4 starch is not specifically mentioned, the selective agent target for reduction is the hydroxyl group for which NaBH_4 is highly selective for.” (Emphasis added.) Answer, page 4. The examiner concludes (Answer, page 4) in view of the teachings of the cited references, it would have been prima facie obvious to use NaBH_4 to reduce a starch. Id.

Claim 11

Claim 11 is directed to a method of preparing a stabilized osmotic agent comprising the following steps: providing a solution of starch dissolved in water; providing a solution of NaOCl ; and adding the NaOCl solution to the starch solution to oxidize the starch.

The examiner relies on Horn for the teaching that oxidation of starch (maltodextrin) leads to a starch product which is more easily solubilized and which exhibits a lower viscosity when solubilized in water and that oxidation may be carried out by utilizing any of a number of oxidizing agents which are synonymous with bleaching agents such as perborates, periodic acid, persulfates and hypochlorite ($-\text{OCl}$). Answer, page 4. The examiner gives no patentable weight to the intended use of the resulting product of the process, a stabilized osmotic agent which can be effectively used in a dialysis solution. Id. See also, Brief, pages 12-13.

The examiner concludes (Answer, pages 4-5):

It would have been prima facie obvious to use NaBH_4 to reduce a starch or NaOCl to oxidize a starch.

Given that these agents have been set forth in the prior art as having a selectivity for the processes of reducing or oxidizing polyols as well as the art recognized advantage of increasing solubility and lowering viscosity (in the case of NaOCl), one of ordinary skill in the art would have been motivated to use these agents for said processes as well as have more than a reasonable expectation of success in the use of these agents for said processes.

In response to both rejections, appellant argues, the cited references “fail to teach or suggest a number of features of the claimed invention, such as stabilizing an osmotic agent.” Brief, page 9. Appellant argues that the examiner has incorrectly failed to give patentable weight to this feature of the claimed invention. Id.

Assuming, arguendo, that the phrase “stabilizing an osmotic agent” is given patentable weight in the claims, we do not find such a treatment of the claims requires a conclusion of claim patentability. It is well settled that from the standpoint of patent law, a compound and all of its properties are inseparable; they are one and the same. In re Papesch, 315 F.2d 381, 391, 137 USPQ 43, 51 (CCPA 1963).

For example, with respect to claim 11, in our view, Horn clearly teaches oxidizing maltodextrin with NaOCl to improve its stability. According to the specification, maltodextrin (a starch) is considered an osmotic agent within the scope of the claims. Because maltodextrin and all of its properties are inseparable; they are one and the same. Thus, Horn discloses a method of stabilizing maltodextrin, and because one of maltodextrin’s properties is that it is an osmotic agent, it can fairly be concluded that

Horn discloses a method of stabilizing an osmotic agent. Thus, we find the examiner has provided sufficient evidence to support a prima facie case of obviousness, which has not been rebutted by appellants.

Similarly, with respect to claim 5, Solomons particularly describes the reduction of D-glucose (the primary component of maltodextrin) to D-glucitol. Eliasson teaches that other non-cellulosic polysaccharides (e.g., arabinoxylans, xyloglucans and glucomannans) are preferentially extracted using aqueous solutions of alkali, containing sodium borohydride. The borohydride converts the reducing end groups of the polysaccharides to a hydroxymethyl group, and this decreases the incidence of alkaline degradation (stabilizes). The cited references, in combination teach decreasing the incidence of alkaline degradation of polysaccharides and reduction of D-glucose (the primary component of maltodextrin) to D-glucitol. In our view, one of ordinary skill in the art at the time of the present invention, upon review of Solomons and Eliasson, would have reasonably concluded that a polysaccharide made up of multiple D-glucose units could be treated with sodium borohydride and water to decrease the incidence of alkaline degradation. We find the examiner has provided sufficient evidence to support a prima facie case of obviousness, which has not been rebutted by appellants.

Claim 17

Claim 17 is directed to a method of preparing a stabilized osmotic agent comprising the following step: dissolving starch in an acid and an alcohol selected from the group consisting of methanol, butanol and glycerol. We agree with appellant that the examiner has failed to put forth sufficient evidence to support a prima facie case of obviousness. Specifically, the rejection fails to address the limitation of dissolving the starch in an acid or alcohol. We do not find that either the Answer or the Final Rejection address the subject matter of claim 17, separately argued by appellants in the Brief. Thus, we do not find that the examiner has presented any evidence to support unpatentability of claims 17-22 for obviousness or otherwise. We are constrained to reverse the rejection of the claims for obviousness as it applies to claim 17.

The rejection of claims 5-16 under 35 U.S.C. § 103(a) as obvious over Solomons in view of Eliasson and Horn is affirmed.

CONCLUSION

The rejection of claims 5-16 under 35 U.S.C. § 103(a) as obvious over Solomons in view of Eliasson and Horn is affirmed. The rejection of claims 17-22 under 35 U.S.C. § 103(a) as obvious over Solomons in view of Eliasson and Horn is reversed.

AFFIRMED-IN-PART

DONALD E. ADAMS
Administrative Patent Judge

DEMETRA J. MILLS
Administrative Patent Judge

LORA M. GREEN
Administrative Patent Judge

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